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Office of Pesticides
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# Pesticide Assessment Guidelines Subdivision I

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## Experimental Use Permits

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# Subdivision I
# Experimenta Use Permits

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# PESTICIDE ASSESSMENT GUIDELINES

## SUBDIVISION I

## EXPERIMENTAL USE PERMITS

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## Foreword

Subdivision I describes procedures for applying for, and testing under, the Experimental Use Permits required by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It is a non-regulatory companion to 40 CFR Part 158, Data Requirements for Registration. Public comment on Subdivision I has been taken in a series of public meetings the last of which was held in July 1982. Data requirements established by 40 CFR Part 158 are discussed in Subdivision I so that it can be read as a complete package and so that Experimental Use Permit application and testing procedures can be explained in their proper context.

# SUBDIVISION I - EXPERIMENTAL USE PERMITS

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# I. ORGANIZATION AND PHILOSOPHY OF SUBDIVISION I

Subdivision I has been organized into three series of sections. The first section series (110) deals with general aspects of permits: scope and intent, definitions, type of testing, and use of cancelled/suspended pesticides. The second section series (111) outlines the specific procedures pertaining to the issuance and use of permits. This includes: labeling and permit requirements; information concerning permit issuance; program surveillance; importation of pesticides; nonissuance and revocation of permits; and publication of notices of permit issuance in the Federal Register. The third section series (112) outlines data requirements (as found in the proposed 40 CFR Part 158 which will be published in final form in 1983) for obtaining a permit.

## A. General.

1. Scope and intent. The scope of these guidelines covers both the testing of a pesticide by any person for the purposes of gathering data necessary to register it under FIFRA sec. 3, and the testing of a pesticide by public or private research agencies or educational institutions for the purpose of experimentation. This experimentation may be agricultural or non-agricultural in nature. The intent of these guidelines is to provide meaningful instructions on the specific data requirements for obtaining an experimental use permit, and to allow for the testing of experimental pesticides while protecting the environment.

2. Definitions. Definitions of terms for these guidelines are the same as those found in Part 172, with two additions: the phrase "public or private research agency or educational institution" and the term "experimental program" are defined for the first time.

3. Testing requiring a permit. Section 110-3 describes those instances when an experimental use permit is required. It also points out exceptions to the requirement for an experimental use permit, with particular emphasis on a substance or mixture of substances being field tested for pesticidal value.

4. Instructions, labeling, and limitations for pesticides not requiring a permit. Section 110-4 provides labeling suggestions for products which do not require a permit. Compliance with these suggestions would help to ensure that substances being shipped for purposes outlined in paragraph (b) of § 110-3 are not labeled in such a way that they could become an object of enforcement action for failure to comply with the requirements of FIFRA.

5. Testing with cancelled and suspended pesticides. Section 110-5 describes the instances when cancelled or suspended pesticides and pesticides which are under intensive Agency review for risks and benefits can be used under a permit.

B. Procedures.

1. General. Section 111-1 details the format for submission of an application for an experimental use permit as outlined on EPA Form 8570-17, "Application for Experimental Use Permit," and clarifies points often misunderstood in the past. In addition, it outlines the review process for experimental use permits and the referencing of data.

Paragraph (b) of § 111-1 explains the 120-day review period mandated by sec. 5(a) of FIFRA. The Agency will attempt to review all applications for experimental use permits within 120 days of receipt. Requests which have been denied may be resubmitted when deficiencies are corrected. Permit requests relying on a pesticide petition for a tolerance, which takes longer than 120 days to review, can be approved prior to the issuance of a tolerance or temporary tolerance with the understanding that the crop will be destroyed if for some reason the tolerance is not established.

Paragraph (d) of § 111-1 discusses how to reference data in support of an experimental use permit. The time restraint placed on the Agency in reviewing experimental use permits makes it mandatory that referenced data be located as quickly as possible.

2. Labeling. Section 111-2 describes the types of labeling which can be used under an experimental use permit. When labeling requirements for registration are applicable to pesticides used under experimental use permits, Subdivision H of the guidelines is referenced. This section explains when supplemental labeling may be used and points out the necessary information which is required to appear on a supplemental label. It also outlines the use of the experimental program as directions for use.

3. Experimental program. The types of information requested in connection with an experimental program are delineated in greater detail in Section 111-3.

4. Permit. Section 111-4 explains the requirements and procedures governing permit issuance, amendment, extension, renewal, and the maintenance of records. This paragraph also states that a request for a time extension/renewal of a pesticide petition (no additional quantity) does not require a fee.

5. Importation of pesticides. Section 111-5 explains requirements relating to the importation of technical material and formulated products for use under an experimental use permit.

6. Program surveillance. The requirements in § 111-6 are essentially the same as those in § 172.8 of the regulations, except that the wording is more explicit. This section points out who is responsible for supervising an experimental program under a permit, the types of information to be submitted, when the information is to be submitted, and to whom it is to be submitted.

7. Refusal to issue, and revocation. Section 111-7 explains the procedures to be followed when the Agency refuses to issue a permit or revokes a permit. This section describes a new procedure which allows the applicant the right to request that reasons put forth in the refusal of a permit be modified or dismissed due to the properties of the pesticide chemical, its proposed use pattern, or other extenuating circumstances. In the event that an applicant wishes to contest a refusal to issue a permit or to contest a revocation of a permit, he is required, within twenty days after receipt of such written notification, to file a written request with the Administrator requesting an opportunity to confer with the Administrator or his designee. The Administrator will then provide the applicant with an opportunity to offer a written statement of facts, explanations, and arguments relevant to the permit refusal or revocation. Within twenty days after the conclusion of a conference, the Administrator will notify the affected applicant of his final decision.

8. Publication. Section 111-8 contains the same requirements as appear in § 172.11 of the regulations, but with elaboration and clarification. The Administrator will publish notice in the Federal Register of receipt of those applications for permits which may be of regional or national significance. He will give prompt notice in the Federal Register of the issuance of an experimental use permit. Determination of whether or not a permit is of regional or national significance can be based on several factors. These include the acreage which is requested under the permit, the amount of pesticide product to be applied per acre, whether the chemical has been suspended or cancelled in the past, and results of the data submitted in connection with the permit.

## C. Data in Support of an Experimental Use Permit.

The data requirements to support experimental use permits have been proposed in 40 CFR Part 158. This rule will be published in final form during 1983. These guidelines describe these data requirements.

The Agency has tried to allow for as much flexibility in data requirements as is feasible. The Agency plans to request only those data necessary to evaluate whether the use of a product under a permit would result in an unreasonable adverse effect on humans or the environment for the duration of the testing period.

The Agency realizes that data requirements should be flexible; that is, data requirements should vary depending on the proposed use pattern and the sites to be tested. While the Agency must, out of necessity, base general data requirements on broad use categories, it does intend to waive data required to support an experimental use permit if the data would not be necessary in evaluating potential hazards to man and the environment arising from use under the permit. Similarly, the Agency may request data in addition to that described in the guidelines, if such data are necessary to determine whether a potential hazard to man or the environment may exist.

Studies which are required to support an application for a permit are generally a subset of those necessary to support registration of a product under sec. 3 of FIFRA. Therefore, in delineating data requirements for experimental use permits, the Agency has chosen only to propose a list of the required tests. Each proposed test is referenced to the appropriate subdivision of the guidelines (Subdivisions D, E, F, G, J, L, and N) which specify the standards for acceptable testing and the information required in the test reports. To reprint the standards for each test would only unnecessarily lengthen these registration guidelines.

1. General requirements. Section 112-1 identifies the general classes of data necessary to support an application for an experimental use permit. It also sets forth standards for data requirements, waivers of data submittal requirements, status of data reviews in connection with a permit, and the potential of hazards to endangered and threatened species. This section clarifies the status of data submitted in connection with a permit application. Since use of a pesticide under an experimental use permit is generally limited and carefully controlled, the data base needed to evaluate the acceptability of an experimental use permit is less extensive than that needed to evaluate a registration application. In some circumstances, data which would not be sufficient to support a registration may be adequate to support a permit. Therefore, an applicant should not assume that since the data had been accepted in connection with an experimental use permit, such data would also be sufficient to meet the requirements for registration (although this will be the case in many instances). When non-acceptance might be likely, the Agency will try to point out those instances to individual applicants. Furthermore, due to the 120-day time restraint placed on the Agency in connection with permit review, data submitted in connection with a permit which are not required to support the permit might not be reviewed. Accordingly, an applicant should not assume that all data submitted in connection with an experimental use permit have been reviewed and found acceptable.

As stated in paragraph (c) of this section, the Agency, in coordination with the U.S. Department of Interior, is likely to deny application for any proposed testing of experimental pesticides -

unless available data or proposed use pattern clearly indicate minimal potential threat) in areas where endangered or threatened species or their critical habitats are known or expected to be present.

2. Product chemistry. Data requirements for product chemistry (§ 112-2) have been divided into two groups: requirements for all uses and requirements for food uses. The data requirements for product chemistry are somewhat flexible. The Agency realizes that, for new chemicals, a manufacturing process has usually not been developed beyond the pilot plant stage. The Agency also realizes that a declaration and certification of ingredient limits may not be possible. Therefore, the data requirements are based,.to some extent, on the information available with respect to the product's stage of development.

3. Environmental fate. Data requirements concerning the fate of a pesticide in the environment (§ 112-3) have been divided into six categories of products: those with terrestrial food crop and noncrop uses; those with forestry uses; those with aquatic food crop uses; those with aquatic noncrop uses; those likely to be discharged directly into aquatic environments; and those likely to be discharged by indirect means or to enter wastewater treatment systems. The data requirements are generally the same as they have been for years, with the exception of the deletion of data requirements for an activated sludge metabolism study, and the requirement that criteria be reviewed to determine the need for a laboratory fish accumulation study. The need for submitting data on a laboratory fish accumulation study is now contingent upon the criteria specified in § 165-4(b)(2) being met or exceeded. These criteria relate to the likelihood of the pesticide active ingredient and/or its principal degradation products reaching water or having a half-life in water greater than 4 days, having an octanol/water partition coefficient greater than 1000, or a having a propensity to accumulate in the organs and tissues of mammals or birds.

4. Human and domestic animal hazards. Section 112-4 describes the toxicity data requirements relating to evaluation of human and domestic animal hazards. These data requirements have been divided into three groups: data required for the use of any pesticide; data required for use of a pesticide which is likely to result in residues on a raw agricultural commodity, food, or feed; and conditional studies required depending on the nature of the pesticide, its use pattern, and/or the results of previously-submitted toxicity data.

When an experimental use permit is accompanied by a petition for a temporary tolerance or temporary exemption from a tolerance, additional toxicity data as indicated in § 112-4(b)(2) are necessary. These data are needed to insure that the public health is protected during the marketing of commodities treated with an experimental pesticide. If the theoretical maximal residue

contribution ("TMRC") 1/ is equal to or greater than 50% of the maximal permitted intake ("MPI") 2/, then additional toxicological information described under § 112-4(b)(2)(iii) is ordinarily required. [The Agency recognizes, however, that this mathematical expression may not have taken into account all relevant factors for all pesticides. Accordingly, the sec. 3 regulations, at § 162.8(a)(3), provide for a waiver of the additional data requirements upon petition by the applicant.] Using this procedure should assure that "adequate" safety data will be available for toxicological assessment of experimental use pesticides whose uses result in residues in or on food or feed. EPA intends to give special consideration to minor uses when the TMRC will exceed 50% of the MPI. The necessity of the additional data outlined in § 112-4(b)(2)(iii) will be determined on a case-by-case basis.

5. Nontarget organism hazards. Section 112-5 outlines toxicology data requirements with respect to nontarget organisms including insects, fish, birds, and mammals. With the exception of the nontarget insect studies, these requirements do not differ from those that have been required over the past several years. The Agency now requires the submission of a honey bee acute contact LD50 and acute toxicity to aquatic insects [§ 112-5(b)(2)]. These are laboratory studies often routinely carried out by basic pesticide chemical manufacturers.

6. Product performance. Section 112-6 outlines product performance data requirements. In general, efficacy data will not be required to support issuance of a permit. Certain exceptions, such as public health uses and uses of cancelled or suspended pesticides, will be handled on a case-by-case basis.

Even though EPA will normally waive efficacy data requirements under § 112-6, the Agency reserves the authority to request on a case-by-case basis the summaries, as well as data, from product performance tests to determine if an extension or renewal of an experimental use permit involving a request for additional quantities of pesticide would be warranted.

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1/ "TMRC" is the amount of a chemical residue which is calculated to remain in an "average" adult human diet. The "average" diet weighs 1.5 kg and is composed of different food items in an amount equal to the calculated average intake for each food item. The TMRC calculation is based on the assumption that the food item contains the maximum level of residue authorized by existing and pending tolerances.

2/ "MPI" is the allowable daily intake (ADI) times 60 kg (average body weight of humans).

7. Minor uses. EPA has developed several policies concerning how it intends to handle minor uses and low-volume pesticides. While these policies deal with registration procedures, they will also be applied to minor use permit applications to the extent that they are applicable. This includes giving priority to a minor use permit application for development of data to support a minor use where no registered alternative is presently available.

## II. ISSUES CONCERNING SUBDIVISION I GUIDELINES

This part of the discussion explains the major issues identified in developing the individual guideline sections of Subdivision I.

### A. Testing Without a Permit, §§ 110-3 and -4.

Over the past few years, many questions have been raised concerning the need for a permit while testing a substance for pesticidal value. Regulations established under 40 CFR Part 172 contain § 172.3(a) which deals with this subject. In these regulations, a substance or mixture of substances being put through laboratory tests, greenhouse tests, or limited replicated field trials, in which the only purpose is to determine its pesticidal value, is not considered a pesticide within the meaning of FIFRA.

Many inquiries have been received concerning the 10-acre limitation established under these regulations with respect to pest/site relationships. Under the old "Land Use" example [§ 172.3(a)(1)], the term "a particular pest" caused confusion. It was not clear whether this allowed for testing of 10 acres per pest per site or 10 acres regardless of pest or site. These proposed guidelines have rewritten this example, doing away with the term "a particular pest." The example is now broken down into three aspects for better clarification: terrestrial uses, aquatic uses, and animal treatments. These guidelines, as now stated, allow for testing against a pest or pests occurring on the same site, at the same time, and in the same locality on not more than ten acres.

A person planning to conduct tests against the same pest in several sites would request a determination from the Agency in accordance with § 110-3(c). Such a request would set forth in writing the reasons why the pesticide may not be efficacious against the same pest when it occurs at two different sites.

Labeling suggestions for pesticides not requiring a permit have been included in these guidelines (§ 110-4). Several commenters have stated that labeling requirements for pesticide products not requiring

a permit are unnecessary and outside the scope of the guidelines. The Agency had contemplated listing label statements which must appear on such labeling. However, the Agency feels that such labeling detail may not be necessary due to the limited use and relatively tight control of such chemicals.

In addition, labeling of such products must be in compliance with Department of Transportation regulations as well as FIFRA sec. 2(q). The Agency has instead listed phrases and statements which should not appear on labels of these pesticides, to prevent confusion with products being used or shipped under an experimental use permit. Preventing this confusion would help preclude certain Agency regulatory enforcement actions that should be directed only toward products that are being moved illegally.

B. Cancelled or Suspended Pesticides, § 110-5

An experimental use permit is the only mechanism available to an applicant or registrant to gather substantial new evidence in connection with a prior cancellation or suspension order. It may also be used to gather additional data in support of a rebuttal of a presumption against registration or intent to suspend or cancel a registration, when such data cannot be gathered through use in accordance with currently registered labels. However, permits will not be issued if the use involves treatment of a food or feed item for which there are no permanent or temporary tolerances, unless the food or feed item will be destroyed. Section 110-5 of this subdivision allows for the testing of pesticide products which have been suspended or cancelled and pesticide products which are under intensive Agency review for a determination of rebuttable presumption against registration (RPAR) or continued registration.

An experimental use permit will be issued for use of a cancelled or suspended pesticide only when the program is designed to gather substantial new evidence which may materially affect the prior cancellation or suspension order, or relative efficacy of alternatives, and when the use will not be expected to cause an unreasonable adverse effect on man or the environment. A commenter has suggested that food or feed treated with a cancelled or suspended pesticide, while being tested under a permit, should always be destroyed. In cases where a tolerance has not been established for the chemical on the crop being tested or when Agency toxicologists believe that treated foods would be unsafe for human or domestic animal consumption, all treated crops will be required to be destroyed.

It is not the Agency's intention that new uses of any cancelled or suspended pesticides fall within the scope of § 110-5. This is because the cancellation or suspension of a pesticide is often based on a use/site/pest relationship, and such a cancellation or

suspension notice would then not apply to a new use. Likewise, the Agency does not consider that new uses of any pesticides that have been presumed against in registration (i.e., when the new use has neither been registered nor previously submitted for registration) fall within the scope of § 110-5. This is because § 162.11 of the registration regulations is intended to cover only registrations and registration applications, not experimental use permits. Applications for new uses of pesticides which have previously been cancelled, suspended, or presumed against in registration, will be handled under routine permit application procedures. However, the Agency will, of course, carry out a careful review of all pertinent data prior to deciding whether permits should be granted for the new uses.

The Agency is aware that a cancellation, suspension, or presumption against registration can be based on data which would be applicable to all uses of a pesticide chemical. In those instances, permit applications for new uses of the pesticide would probably be denied. However, in some cases, data on which a cancellation, suspension, or presumption against registration is based does not apply to all uses, and such uses must then be considered on their own individual merits.

C. Labeling, § 111-2.

Several questions were raised in connection with the labeling requirements in § 111-2(a). Commenters questioned the requirement for an appropriate limitation on entry of persons into treated areas. They also pointed out that the data necessary to establish reentry intervals are generally not available for new pesticide chemicals at the time of permit use, and thus compliance is impossible. In addition, fields must often be entered to collect data required for registration under FIFRA sec. 3; this activity can be in conflict with the reentry limitations. The Agency has reviewed this aspect and agrees that reentry information may not be available. EPA has written this part to allow for adequate precautions concerning protective clothing in lieu of a reentry interval. Due to the limited and controlled use under a permit, such precautions should alleviate potential problems associated with reentry while at the same time allow for gathering of the necessary data for future registration. See also part II.M. of this Discussion for further discussion on reentry.

Under this same section, the requirements for a crop rotation interval (the time interval between treatment of a crop with a pesticide and the planting of a new food crop) were questioned. Some commenters believe that crop rotation intervals are too restrictive. They point out that such data are generally not available at this stage of a product's development. The alternative, an 18-month rotation restriction on the label, was considered unreasonable since

most farmers will not allow land to stand idle for this length of time. While the Agency understands the concern over such a labeling restriction, it cannot ignore the possibility of illegal residues occurring in crops rotated with treated crops. Lack of an appropriate crop rotation restriction can result in such illegal residues of a pesticide. Crops harvested with such illegal residues are subject to confiscation and destruction under the Federal Food, Drug, and Cosmetic Act. The Agency points out that crop rotation data gathered during the permit period may be submitted at any time. Upon assessment of such data, a determination will be made as to whether the restriction should be modified or deleted.

D. State Permit or License, § 111-4(a)(3).

With the exception of a Federal agency testing on Federal land, the granting of a Federal permit to ship and use a pesticide would not eliminate the need for a permittee to obtain individual state permits or licenses from the states in which he will be conducting testing. Failure or refusal to obtain a required State permit or license would result in the modification of a Federal permit by deletion of testing sites in any state where a permit or license has not been obtained. Similarly, if a state refuses to grant a permit or license for use of a pesticide product, such refusal would override the Federal permit, with respect to that state.

E. Notification of Issuance of an Experimental Use Permit, § 111-8(c).

Under § 111-8, the Administrator will give prompt notice in the Federal Register of the issuance of an experimental use permit. Among other things, this notice will include a statement indicating where the permit is available for public inspection. Due to FIFRA sec. 10, the only information which will be made available to the public is the labeling for the product and part of the letter of permit issuance. Since the letter issuing a permit often contains information concerning the product's development and may be proprietary in nature, only that part of the letter dealing with effective dates, quantity of product, tolerance establishment (if applicable), states to which the product may be shipped, and statements concerning the acceptability of the labeling are to be available for inspection. All other information would have to be obtained through procedures set forth in the Freedom of Information Act.

F. Data Requirements in General, Series 112.

Requirements for data to support a permit application vary, depending on the proposed use. That is, agricultural uses generally

require more data than indoor uses. However, indoor uses at times may require types of toxicology or exposure data that are different and more extensive than those for outdoor uses due to significant potential exposure to humans. The data requirements are based on potential exposure to man and/or the environment. Depending on this potential exposure from the proposed use, additional data or different types of data may be required.

G. Product Chemistry Data Requirements, § 112-2.

The Agency must have certain chemistry data to evaluate pesticide products submitted for permits. However, since many products are in an early stage of development when a permit is requested, data which are generally required concerning the manufacturing process, unintentional ingredients, ingredient limits, and product analytical methods may not be available to the extent required for registration of such a chemical. Commenters have suggested that certain allowances be made in those cases when the data have not yet been developed for new pesticide products.

The Agency understands that data concerning the manufacturing process, unintentional ingredients, ingredient limits, and analytical methods may not be available for new pesticide products at this stage of their development. In such cases, the Agency believes that the following information is sufficient, in connection with an experimental use permit:

1. In lieu of a full description of the manufacturing process, a schematic diagram and brief description of the manufacturing process should be submitted for a pesticide product which is in the development stage. For registered pesticides, a full description of the manufacturing process is required.

2. A discussion of unintentional ingredients, when available, and declaration and certification of ingredient limits are required for established pesticide products only.

3. In lieu of full product analytical methods and data, rudimentary analytical methods and data are required. For established pesticide chemicals, analytical methods and data would be required, when available.

H. Ninety-Day Feeding Studies, § 112-4(b)(2).

The Agency has requested, for many years, two 90-day feeding studies (one employing a rodent and one a nonrodent) which establish

a "no observed effect level" (NOEL), in connection with permit applications accompanied by a petition for temporary tolerance(s). This requirement remains unchanged as set forth in § 112-4.

A commenter, however, has suggested that this requirement may be excessive for the initial establishment of a temporary tolerance in its first year. He believes that two 4-week studies should suffice for the temporary tolerance and that, prior to an extension or renewal of the tolerance, results of the two 90-day studies be submitted.

Whenever the use pattern of a pesticide results in repeated human exposure to the product, its active ingredient, metabolites, or degradation products, through an oral route of exposure, the Agency believes that the minimum amount of subchronic toxicity data needed to support such a use would still be two 90-day feeding studies from which a NOEL can be established. These studies are generally conducted on the active ingredient, but may be requested on major metabolites or degradates in certain instances.

I. Acute Inhalation and Dermal Sensitization Studies, § 112-4(b)(3).

The Agency requires the submission of a dermal sensitization study and an acute inhalation study in support of a permit when these studies are required to support registration.

J. One-Year Interim Report on a Chronic Feeding Study, § 112-4(b)(2).

In the past, the Agency has requested, in addition to acute and subchronic data, information from ongoing or completed chronic toxicity studies in support of a petition for temporary tolerance(s), when residue levels of a product exceeded 0.1 parts per million (ppm) in or on a raw agricultural commodity. This was because residues higher than 0.1 ppm were expected to present a higher degree of risk to man through oral ingestion of the treated commodity than would residues of 0.1 ppm or less (an arbitrary breakpoint).

The Agency has decided to replace the 0.1 ppm criterion level. In its place is a system which estimates potential risk to man based on residue levels of the product in or on raw agricultural commodities and on the toxicologic potency of the product. This more realistic approach to estimating risk considers the independent nature of both of these variables and the relative relationship between them. The system involves use of the TMRC (theoretical maximal residue contribution) and the MPI (maximal permitted intake). (These terms are explained in part I.C.4. of this Discussion.) The higher degree of potential risk ordinarily warrants submission of additional toxicology data. Therefore, in such cases, a one-year interim report

on a chronic feeding study and a first-generation interim report on a reproductive study are required.

For products with established tolerances, the TMRC is calculated from the cumulative total residues of the product in or on all treated crops with existing and pending tolerances. The MPI is ordinarily derived from the NOEL (no observed effect level) determined in chronic toxicity studies already submitted to the Agency in support of the established tolerances. When the TMRC exceeds 50 percent of the MPI and sufficient chronic data are not available, a judgment is made on the adequacy of the entire toxicologic data base supporting the proposed use. The judgment would include consideration of the incremental increase in exposure resulting from the proposed use. Only when sufficient toxicologic information is not available or the increase in exposure is significant would additional data from chronic studies be required.

For products without established tolerances, the TMRC is calculated from the proposed use and other pending tolerances. The MPI is usually derived from the NOEL observed in chronic toxicity studies. In the absence of chronic studies, the MPI may be derived from a NOEL observed in subchronic studies and an appropriate safety factor. When the TMRC exceeds 50 percent of the MPI and the anticipated exposure resulting from the proposed use is significant, interim reports on chronic feeding and reproductive studies are required.

Following a careful review of toxicology studies required in the past to support temporary tolerances, 50 percent of the MPI was selected as the breakpoint that is most consistent with prior Agency policy on toxicity data requirements. The intention of the new system is not to appreciably alter the studies required, but rather to provide a more realistic and scientifically-supportable means for estimating potential risk to man. Estimation of this risk necessitates consideration of the inherent toxicity of the product as well as residue levels of the product in or on raw agricultural commodities. The Agency realizes that other relevant factors, particularly those relating to exposure, must also be taken into account when determining the need for additional toxicity information. Therefore, the Agency considers the 50 percent limit to be a flexible guidepost subject to reasonable variation on a case-by-case basis.

## K. Product Performance, § 112-6.

Section 3(c)(5) of the amended FIFRA provides that the Administrator may waive data requirements pertaining to efficacy. The Agency intends to operate on a policy of requiring submittal of efficacy data on a case-by-case basis for those products having uses of known public health significance (as defined in § 162.18-2

(d)(2) and (3) of the FIFRA regulations], and waiving efficacy data submittal requirements in connection with all other uses. (Refer to § 90-1(b) of Subdivision G for details concerning waiver of efficacy data submittal requirements.)

In general, those uses for which product performance will be waived for registration will also be waived in connection with experimental use permits. Exceptions involve permit extensions, renewals, or requests for additional quantities under a permit. Registrants may also choose to apply for experimental use permits to test for pesticidal efficacy in those cases when residue data related to tolerance applications can be gathered simultaneously. Product performance data may be required on an exceptional case basis so that an evaluation of the need for additional testing under a permit can be made.

## L. Maintenance of Records.

The Agency currently requires all producers of pesticides, produced in connection with a permit, to maintain records in accordance with 40 CFR Part 169. The Agency considers that such records, if accepted later in connection with registration, would become part of the history of an application and should be maintained for as long as the registration is valid. Such records may be held as microfilmed copies, however, provided that the recordkeeper certifies that such microfilmed records are complete and legible.

## M. Reentry Data.

Requirements for data on field residues, exposure, and toxicology to establish reentry levels appear in Subdivision K, Exposure Data Requirements: Reentry Protection. The Agency requested public comments in the process of establishing reentry intervals (43 FR 37350; 8/22/78). The Agency's position at present is not to designate any reentry data requirements for a permit application, only for a registration application.

## N. Gene Mutation Tests.

Currently, the Agency requires, at § 112-4(b)(2)(ii)(C), a battery of three mutagenicity studies to assess gene mutations, chromosome aberrations, and primary DNA damage, in support of a permit where the product will be used on food or feed.

# EXPERIMENTAL USE PERMITS

## Series 110: GENERAL

### § 110-1 Scope and intent.

(a) Authority. The Administrator of EPA is authorized by FIFRA sec. 5(a) to issue an experimental use permit if he determines that an applicant needs such a permit in order to accumulate information required by FIFRA sec. 3. (This includes development of efficacy information for the purpose of ensuring that labeling submitted for registration contains directions for use which are necessary and sufficient for the product user to achieve the expected pest control results.) The Administrator is also authorized under FIFRA sec. 5(g) to issue an experimental use permit to any public or private agricultural research agency or educational institution for purposes of experimentation.

(b) Purpose of sec. 5. The purpose of FIFRA sec. 5 is to regulate the extensive testing of prospective pesticide products when such testing is for the purpose of developing data to support an anticipated product registration or label, or when such testing is for the purpose of undertaking experimental field research conducted by research agencies and educational institutions. The law permits this pesticidal use of such products which have not first been registered. Products covered by this regulation are limited to those that require field testing in order to accumulate the necessary information for prospective registration. Section 5(d) of FIFRA provides that, in the case of a pesticide containing any chemical or combination of chemicals which has not been included in any previously-registered pesticide, the Administrator may specify that studies be conducted to determine whether the testing of a pesticide, containing a chemical or combination of chemicals not included in a previously-registered pesticide, under a permit may cause unreasonable adverse effects on humans or the environment.

(c) Intent. The intent of these guidelines is to amplify the requirements set forth in the regulations (40 CFR Part 172) concerning the procedures and basic data requirements for issuance of an experimental use permit.

(d) Purposes. (1) Permit. The purpose of an experimental use permit is to allow testers to use their prospective products under extensive, controlled, field or actual use conditions, so that they can develop data necessary to evaluate efficacy and potential for safe use or adverse effects on humans and the environment. Most of these data would eventually be used to support applications for registration of the prospective products.

(2) Subdivision I. The purposes of this subdivision are:

(i) To provide pertinent information and instructions to both

applicants for experimental use permits and the public, relative to four major subjects:

(A) Current permit procedures;

(B) Data and labeling requirements for experimental use permits

(C) Acceptable test methods for the development of required data; and

(D) Information required in reports from testing under an experimental use permit.

(ii) To enable applicants to improve the quality, completeness, and consistency of permit applications, thus permitting an efficient review of applications; and

(iii) To assure that both data development and review are based on a uniform set of standards.

(e) Distribution. Pesticides under experimental use permits may not be sold or distributed other than through participants. When sold or distributed through participants, such pesticides may be used only at an application site of a cooperator and in accordance with the terms and conditions of the experimental use permit. Pre-registration marketing programs for pesticides do not fall within the scope of FIFRA sec. 5 nor do indefinite renewals of experimental use permits as a substitute for full registration.

§ 110-2 Definitions.

Terms used in this subdivision, except the term "applicant," shall have the meanings set forth in FIFRA, at § 162.3 of the FIFRA sec. 3 regulations, and at § 60-2 of Subdivision D. In addition, for the purposes of this subdivision:

(a) The term "applicant" means any person who applies for an experimental use permit, pursuant to sec. 5 of the Act.

(b) The term "permittee" means any applicant to whom an experimental use permit has been granted.

(c) The term "cooperator" means any person who grants permission to a permittee or a permittee's designated participant for the use of an experimental use pesticide at an application site owned or controlled by the cooperator.

(d) The term "participant" means any person acting as a representative of the permittee and responsible for making available

for use, or supervising the use or evaluation of, an experimental use pesticide.

(e) The phrase "value for pesticide purposes" means that characteristic of a substance or mixture of substances which produces an efficacious action on a pest.

(f) The phrase "public or private research agency or educational institution" means any organization engaged in research pertaining to the use of pesticides, or any educational institution engaged in pesticide research. Any research agency or educational institution whose principal function is to promote, or whose source of income is directly derived from, the sale or distribution of pesticides (or their active ingredients) does not come within the meaning of this term.

(g) The term "experimental program" means the plans and procedures of all activities to be carried out under the auspices of an experimental use permit.

(h) The term "residential areas" means those areas where an application of a pesticide is to be made directly to humans or pets or where application of a pesticide is to be made in, on, or around all structures, vehicles, or areas associated with the household, home life, or noncommercial areas where children spend time. These areas include but are not limited to:

(1) Gardens, non-commercial greenhouses, yards, patios, houses, pleasure marine craft, mobile homes, campers and recreational vehicles, non-commercial camp sites, home swimming pools, and kennels;

(2) Articles, objects, devices, or surfaces handled or contacted by humans or pets in all structures, vehicles, or areas listed in paragraph (h)(1) of this section; and

(3) Educational, lounging, and recreational areas of preschools, nurseries, schools, and day camps.

§ 110-3 Pesticide uses for which an experimental use permit is required.

(a) General. Except as provided by paragraph (b) below, an experimental use permit will be required for the use of: (1) An unregistered pesticide; or (2) A registered pesticide when used in a manner inconsistent with its labeling, as defined under FIFRA sec. 2(ee).

(b) Exceptions. (1) When a permit is not required. An experimental use permit will not be required when:

(i) A pesticide is being used in accordance with an exemption from requirements of the Act issued by the Administrator under FIFRA sec. 18;

(ii) Testing of a pesticide is authorized by a state under FIFRA sec.5(f) [testing of a pesticide under sec. 5(f) must be in accordance with Subpart B of Part 172]; or

(iii) A pesticide is being put through laboratory or greenhouse tests, or limited replicated field trials; and

(A) The purpose of the test(s) is only to determine the value of the substance for pesticidal purposes or to determine its toxicity or other properties;

(B) The producer, applicator, or any other person conducting a test does not expect to receive any immediate benefit from the pest control caused by the use of the substance in the test; and

(C) The product will not be used in residential areas where it will be accessible to the general public, either in its packaged form or after application.

(2) Examples of uses for which a permit is not required. For purposes of paragraph (b)(1)(iii) of this section, the Agency will presume that the following types of tests do not require an experimental use permit. Tests outside the following categories do not necessarily require an experimental use permit. However, with respect to tests outside the scope of the categories described below, the user must be prepared to show that the test falls within the scope of paragraph (b)(1)(iii) of this section.

(i) Terrestrial use. (A) Tests which are conducted on a cumulative total of not more than 10 acres, provided that:

(1) When more than one intended target pest occurs at the same time in the same locality, the 10-acre test shall encompass all of the intended target pests; and

(2) When more than one target pest is intended, and they do not occur at the same time or in the same locality (or application of the pesticide would not be at the same time), up to 10 acres may be treated for each target pest.

(B) Any food or feed crops involved in, or affected by, such tests (including, but not limited to, crops subsequently grown on such land which may reasonably be expected to contain residues of such substance or mixture) shall be destroyed or consumed only by

experimental animals; or

(C) A tolerance or exemption from a tolerance has been established for residues of the substance on the food or feed crop involved, and such tolerance will not be exceeded.

(ii) Aquatic use. Tests conducted on a total of not more than one surface-acre of water, provided that:

(A) Waters which are involved in, or which are affected by, such tests will not be used for irrigation purposes, drinking water supplies, or body-contact aquatic recreational activities; and

(B) No such test may be conducted in any waters which contain, or which affect, any fish, shellfish, or other animals or plants taken for recreation or commercial purposes and used for food or feed unless a tolerance has been established and will not be exceeded, or unless an exemption from the requirement for a tolerance has been established.

(iii) Animal treatments. Tests shall be conducted only on experimental animals that will not be used as food or feed unless:

(A) A tolerance or exemption from a tolerance has been established for any food (meat, fat, meat byproducts, eggs, and/or milk) produced from the animal which is likely to contain residues; and

(B) The tolerance will not be exceeded.

(C) Request for determination. Any person who is uncertain as to whether testing may be conducted without a permit may submit a request for determination to the Agency. Such a request shall include all information pertinent to the proposed use and a summary of all information known about the pesticide.

§ 110-4 Instructions, labeling, and limitations for pesticides not requiring a permit.

(a) Instructions. (1) Pesticides which are exempt from the requirement to obtain an experimental use permit under § 110-3(b)(1)(iii) of this subdivision should contain instructions necessary to carry out the intended testing. These instructions should be provided separately from the label on the container.

(2) Instructions should not include pesticidal claims. For example, one cannot say "To control (pest), apply..."; one can say "To study effects of this product on (pest), apply..."

(b) Labeling. Labeling of non-registered pesticidal chemicals should not bear:

(1) Any pesticidal claims, either expressed or implied.

(2) A product identification (product name) which expresses or implies pesticidal intent or value.

(3) Directions for use expressing or implying pesticidal intent.

(4) The words "For Experimental Use Only" (inferred association with EPA Experimental Use Permit). However, the phrase "For research purposes only" might be appropriate.

(c) Limitations. Unregistered pesticide products which do not require an experimental use permit under § 110-3(b)(1)(iii) of this subdivision:

(1) Are still subject to the Hazardous Materials Transportation Act and the Endangered Species Act. Studies with pesticides shall not be conducted in areas containing, or suspected of containing, threatened or endangered plants or animals or their critical habitats. When there is some question as to whether such organisms may be affected by prospective testing, the appropriate staff in the U.S. Department of Interior shall be notified.

(2) Are limited in use to such studies as are necessary to support an experimental use permit and its labeling. This limitation would not apply to public or private agricultural research agencies or educational institutions.

§ 110-5 Experimental use permits for pesticides under intensive review of risks and benefits, and for cancelled or suspended pesticides.

(a) Pesticides under intensive review of risks and benefits. An experimental use permit for use of a pesticide which is under intensive evaluation due to a rebuttable presumption against registration (RPAR) may be issued, provided that the proposed use will not result in an unreasonable adverse effect on man or the environment, and:

(1) The proposed use does not involve treatment of a raw agricultural commodity or feed or food item; or

(2) The proposed use does involve treatment of a raw agricultural commodity or feed or food item, and:

(i) Treated raw agricultural commodities or feed or food items will be destroyed or used for research purposes only; or

(ii) Treated raw agricultural commodities have permanent or temporary tolerances or exemptions from tolerances for residues of the active ingredient in accordance with 40 CFR Part 180; treated feed or food items have food additive regulations established for residues of the active ingredient in accordance with 21 CFR Part 193 and/or 561; and all inert ingredients are cleared in accordance with 40 CFR Part 180 Subpart D.

(b) Cancelled or suspended pesticides. An experimental use permit may be issued for use of a pesticide at a site and on a pest for which registration has been cancelled or suspended, provided that this use satisfies the requirements of paragraph (a) of this section, and the proposed experimental program is designed for the purpose of gathering substantial new evidence which may materially affect a prior cancellation or suspension order, or to establish relative efficacy of alternatives.

Series 111: PROCEDURES

§ 111-1 General requirements.

(a) Experimental use permit applications. An application for an experimental use permit must be submitted in triplicate. Each of the three copies must be set up in bound removable sections lettered A through G with margin tabs. A completed experimental use permit application shall consist of:

(1) Application form. A completed application form for an experimental use permit, EPA Form 8570-17, or a more recent equivalent.

(i) If an EPA company number (item 2) has not been previously assigned, indicate "none," and a number will be assigned.

(ii) Third party applicants (those who will be testing another firm's registered product) need not complete item 11 on the form.

(iii) If a registered pesticide is being tested and the material will be purchased locally, items 5 and 10 on the form may be left blank.

(iv) Item 8 "product" means pounds (avoirdupois weight) or gallons of formulated product, and pounds of "active equivalent" means pounds of active ingredients.

(v) Item 9 on the form "Proposed period of shipment/use." Give time for shipment of material, and the actual anticipated use season. Note: whenever possible, the Agency will use the earliest date listed as the effective date for the permit.

(2) Product chemistry data. Section A of the application shall contain the chemical and physical properties of the chemical being tested, and a completed confidential statement of formula, EPA Form 8570-4. Refer to § 112-2 for the types of information required in this section.

(3) Labeling. Section B shall contain the product's labeling to be used under the permit. Refer to § 111-2 for the types of information required to appear on labeling, and the types of labels which may be used.

(4) Toxicology data. Section C shall contain pertinent toxicity data with respect to human and domestic animal safety and nontarget organism hazards. Section C shall consist of two parts: C1 and C2. Part C1 shall contain data on the toxicity of the pesticide to humans and domestic animals, and part C2 shall contain data on the toxicity of the pesticide to nontarget organisms.

Refer to §§ 112-4 (for part C1 data) and 112-5 (for part C2 data) for the individual studies to be required.

(5) Residue and environmental data. Section D shall consist of three parts: D1, D2, and D3.

(i) Part D1 shall contain residue data for food or feed commodities [refer to paragraph (d) of this section]. If the permit is accompanied by a pesticide petition, residue data on food/feed commodities may be referenced to Section D of the pesticide tolerance petition.

(ii) Part D2 shall consist of residue data on:

(A) Nonfood crops such as tobacco (refer to Subdivision O), and

(B) Foliage or other sites which may relate to worker hazards or adverse effects on the environment (refer to Subdivisions K and N).

(iii) Part D3 shall consist of appropriate environmental fate data on the effects of the chemical on the environment. Refer to § 112-2 for the types of environmental fate data required.

(6) Product performance data. Section E shall consist of:

(i) Information necessary to justify the proposed label contained in Section B, program dosage rates, and quantity of material requested; and

(ii) Phytotoxicity data, unless waived by the Agency in accordance with § 120-1(b) of Subdivision J of these guidelines, and data concerning adverse effects on inanimate articles or surfaces.

(7) Tolerance proposal. Section F shall consist of:

(i) A statement to the effect that the use proposed is a nonfood use; or

(ii) A statement that the food or feed will be destroyed or used for research purposes only, as well as the type of testing in the case of research (the Agency will assume that the applicant is aware of the cost involved in destroying a crop); or

(iii) Appropriate citation to:

(A) Appropriate temporary tolerance proposal, if the permit will authorize use on a new food or feed crop [refer to paragraph (d) of this section];

(B) 40 CFR Part 180, if the permit will authorize use on a raw

agricultural commodity for which a tolerance has been established, and the appropriate rationale to support the fact that the new use pattern will not require an increase in the existing tolerance; or

(C) 21 CFR Part 193 or 561, if the permit will authorize a use for which a food or feed additive tolerance has been established.

(8) Proposed testing program. Section G shall consist of a full description of the proposed testing program to be carried out under the experimental use permit. Refer to § 111-3 for the types of information required in an experimental program.

(b) Experimental use permit review. (1) General. Upon receipt of a complete application [refer to paragraph (a) of this section] for an experimental use permit, the Agency will review the submitted data and within 120 days notify the applicant of the Agency's decision. A permit application that is accompanied by or relying on a pesticide petition for a tolerance may necessarily be granted on a crop destruct basis pending the completion of tolerance review. The Agency will try to review the tolerance petition within the 120-day period.

(2) Incomplete applications. The Agency will deny an application for a permit which the Agency finds incomplete (refer to § 111-7 of this subdivision). The Agency will hold the application for a permit for 30 days after it has notified the applicant both of its denial and its statement delineating the kinds the information needed to complete the file for the permit. The application may then be withdrawn by the applicant or returned to him by the Agency unless:

(i) The information necessary to complete the application is submitted; or

(ii) A letter is received from the applicant requesting that the application be held by the Agency for a specified period of time. This time period is not to exceed six months. At the expiration of the specified time period, the application may be returned to the applicant or withdrawn by the Agency.

(3) Resubmissions. Applications which are submitted, found complete, reviewed, and refused for reasons outlined in § 111-7 may be resubmitted.

(c) Petition for tolerance. (1) Pesticide petition. An application for a permit to use an experimental pesticide on a raw agricultural commodity must be accompanied by a petition for temporary tolerance (or exemption from a tolerance) unless there is a tolerance (for that pesticide on the commodity) which will not be exceeded or unless the commodity will be destroyed or used only for research purposes. A petition for a temporary tolerance shall be

accompanied by an advance deposit to cover fees as provided by 40 CFR 180.33. Temporary tolerances are established under authority of sec. 408(j) of the Federal Food, Drug and Cosmetic Act.

(2) Food additive petition. If the pesticide product will be used in or on feed or food, it must be accompanied by a petition for a food or feed additive tolerance. Food or feed additive tolerances are established under authority of sec. 409 of the Federal Food, Drug, and Cosmetic Act.

(3) Data in support of petition. A petition for a temporary tolerance (or exemption from a tolerance) or a petition for a food or feed additive tolerance shall contain such data as are available on the subjects outlined in clauses (A), (B), (C), (D), (E), (F), and (G) of 40 CFR 180.7(b).

(d) Referencing data. (1) Data that may be referenced. Data required under Sections A, C, D, E, and F of an application for an experimental use permit may be referenced if the data have previously been submitted in connection with an experimental use permit, an application for registration or amended registration, or a petition for a pesticide tolerance.

(2) Information which shall not be referenced. Section B (labeling) and G (experimental program) shall not be referenced.

(3) Information necessary to reference data. When referencing previously-submitted data, the following information must be included:

(i) Appropriate accession number(s) assigned by the Agency;

(ii) The number or file symbol of the experimental use permit, registration, and/or petition with which the data are associated; and

(iii) The date the data were submitted.

(4) Referencing by public or private agencies. Public or private research agencies and educational institutions need only include the registration number of a product when referencing data; however, if data are not referenced as indicated under paragraph (d)(3) of this section, the Agency's required 120-day limit for review of an application may have to be extended.

§ 111-2 Labeling.

(a) General. Except as provided by paragraphs (b) and (c) of this section and § 111-5 of this subdivision, every pesticide product under an experimental use permit shall bear a label containing

the following information. In addition, labeling must be in compliance with §§ 100-3 through -9, and -11, Subdivision H, except where negated by the requirements of this section. The label shall include:

(1) The prominent statement "For Experimental Use Only."

(2) The Experimental Use Permit number.

(3) The statement "Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use."

(4) The name, brand, or trademark of the product [refer to § 100-7(a)(2)].

(5) The name and address of the permittee, producer, or registrant [refer to § 100-7(c)].

(6) The net contents [refer to § 100-7(e)].

(7) An ingredients statement [refer to § 100-7(h)].

(8) Hazard Warnings and Precaution Statements.

(i) All labels under an experimental use permit must carry the following:

(A) A signal word ("Danger," "Warning," or "Caution") based on the acute toxicity of the product;

(B) The phrase "Keep Out of Reach of Children" (except in the case of products that have no likelihood of coming in contact with children during storage, handling, or application;

(C) A precautionary paragraph warning the user of hazards which may be encountered in handling, storing, using, or disposing of the pesticide based on the toxicity of the product and its proposed use;

(D) Appropriate first aid treatments and antidotes, if available; and

(E) Environmental hazard statements.

(ii) The signal word and the phrase "Keep Out of Reach of Children" must be in the proper type size and appear on the front panel of the label. The precautionary and first aid statements may appear elsewhere as long as they are referenced on the front panel.

(iii) Refer to § 100-8 of Subdivision H for additional

information concerning hazard warnings and precaution statements.

(9) Appropriate limitations (if known) on entry of persons into treated areas, or a label statement requiring adequate protective clothing. (Refer to Subdivision K.)

(10) The establishment registration number, except in those cases where:

(i) Application of the pesticide is made solely by the producer [refer to § 167.2(a) of the regulations]; or

(ii) The establishment registration number is stamped on the product container. [Refer to § 100-7(g) of Subdivision H.]

(11) Directions for use. Directions for use on an experimental use permit label must contain the following information:

(i) Crop(s) or site(s) on which the product is to be used;

(ii) The pest(s) which the product is be used against, or response the product is intended to induce;

(iii) The dilution and/or application rate(s) to be used;

(iv) The method(s) of application to be used, including types of application equipment involved;

(v) The timing of application, including timing intervals;

(vi) Pre-harvest intervals when crops are to be treated;

(vii) A crop rotation interval unless data have been submitted showing no pesticide residue carryover;

(viii) A statement concerning proper storage and disposal of the pesticide and its container that incorporates the methods specified in § 111-3(a)(8); and

(ix) Any other information necessary to assure safe and effective use of the product for its intended purpose.

(12) A misuse statement. This consists of a statement that use of the pesticide inconsistent with the terms of the experimental use permit is a violation of Federal law.

(b) Experimental program as directions for use. When the experimental program contains directions for use, the label shall state that the product must be used according to the directions in the experimental program. In addition, the program must accompany the product and contain the following:

(1) The statement "For Experimental Use Only";

(2) The statement "This program must be in the possession of the user at the time of pesticide application"; and

(3) The EPA Experimental Use Permit Number.

(c) Supplemental labeling. Supplemental labeling (labeling used in connection with a registered label) describing the prospective use under a permit may be used only in connection with an already-registered product and shall contain the following information:

(1) The prominent phrase "For Experimental Use Only";

(2) The statement "Supplemental Labeling for the Experimental Use of (Product Name), EPA Reg. No. _____, on/in (crop)_____ (or site) _____)." (The name of the registered product, the product's registration number, and the crop or site shall be filled in.);

(3) The statement "For use only at an application site of a cooperator and in accordance with the terms and conditions of the Experimental Use Permit";

(4) Directions for use or a statement referring the user to the experimental program for directions for use;

(5) The statement "All applicable directions, restrictions, and precautions on the EPA-registered label are to be followed";

(6) The statement "This labeling must be in the possession of the user at time of pesticide application";

(7) The EPA Experimental Use Permit Number; and

(8) The name and address of the permittee.

(d) Language. The language used on labeling shall be in compliance with § 100-6(g) of Subdivision H.

(e) Prominence and legibility. With respect to prominence and legibility of the print, all labeling shall be in compliance with § 100-6(c) of Subdivision H.

(f) Point source discharge. Products under an experimental use permit which are used in a manner that might result in a point source discharge into a body of water must carry the following precaution: "Do not discharge into lakes, streams, ponds, or public waterways unless in accordance with an NPDES permit. For guidance, contact your Regional Office of the EPA."

(g) Department of Transportation labeling requirements. The Department of Transportation (DOT) has labeling requirements for the shipping containers of pesticide products. See 49 CFR Parts 170-189. Registrants may incorporate the DOT hazard symbol (commonly called a "DOT diamond") in their product label if they so desire, provided it remains separate and distinct from that labeling required by EPA.

(h) Claims. (1) Since experimental use permits are issued, in part, to gather efficacy data, claims such as "controls," "suppresses," or "repels" must be modified to reflect that the product is being evaluated for such purposes, i.e., "to evaluate control of," "to evaluate suppression of," or "to evaluate repellency of" pest, growth, or behavior. Such modification of claims must take place throughout the label.

(2) There may be no false or misleading statements on the label. Refer to § 100-5(b) of Subdivision H for information concerning false and misleading statements.

(i) (Reserved)

(j) Warranty. Statements expressing or implying that use of a product is beyond the control of a permittee are not allowed. The use of a pesticide under an experimental use permit must be under the total control of a permittee. Refer to § 100-5(b)(1) of Subdivision H for additional information concerning warranties.

§ 111-3 Experimental program.

(a) Required program information. The experimental program in support of an application for an experimental use permit shall contain the following information:

(1) Participants and cooperators. (i) The names and qualifications of the individual participants who will be supervising the experimental work.

(ii) The names, addresses, and telephone numbers of cooperators as they become available. Applicants must certify that the cooperators and participants listed have been contacted and have agreed to participate in the experimental testing.

(2) States and acreage. (i) The states and territories in which the pesticide will be used, along with the approximate amount of product, active ingredient, and acreage to be treated in each state, and estimated number of test locations. When possible, give the counties in each state where testing will take place. When acreage does not apply, give the extent of testing per state in

more appropriate terminology. States to which the product will be shipped for further distribution must be identified.

(ii) EPA normally will advise proper officials in the affected States within seven days of issuance of the permit and in any case prior to the scheduled date of use.

(3) Program details. The details of the proposed program, including:

(i) A general description of the procedures and types of data planned to be collected during the test program. Note: submission of a description of the pest control evaluation procedures to be used in assessing the level of pest organism(s) or damage in test plots is recommended, since the appropriate procedures and criteria will vary for each use pattern.

(ii) The target pests or organisms the product is to be tested against, or the type of plant regulator, desiccant, or defoliant;

(iii) The crops, animals, surfaces, materials, buildings, or sites to be treated;

(iv) The approximate size and number of tests (including replicates) per state; and

(v) For seasonal pests and crops, the desired months for pesticide application(s), the use pattern, intended plot sizes, number of replicates, dosage rates, method of application, season of use, and timing of application (preplant, postemergence, multiple, and similar information).

(vi) The proposed experimental program, including number of years of proposed testing and the number of persons available to supervise the program.

(4) Objectives. The specific and detailed objectives of the proposed program (i.e., type(s) of data to be collected, such as performance, yield, phytotoxicity, and environmental residues). Indicate long-range testing plans, including how many years of experimental testing are planned.

(5) Applications higher than label rate. Applications at a higher-than-label rate, for such purposes as phytotoxicity and residue testing, shall be delineated. This shall include rates, acreages, and, for food uses, disposition of treated crops or animals. (See § 121-1(b)(3) of Subdivision J for phytotoxicity testing rates.)

(6) Quantity of product. The maximum quantity of product to be authorized under an experimental use permit shall be sufficient

to allow for the generation of all test results necessary to support intended label claims. Requests for amounts that appear to be excessive or that have no justifiable rationales will either be denied or reduced by the Agency to amounts which are adequately justified by the information submitted.

(i) The following criteria should be used by an applicant to determine the quantity of pesticide needed for use under a permit:

(A) The label variables being proposed by the applicant, such as dosages, pests, frequency of application, method(s) of application, crop(s), site(s), use pattern, pest/crop/site distribution, and cultural or industrial practices;

(B) The test plot size, replication, geographical distribution, and number of plots per variable being considered; and

(C) Registration test standards and requirements.

(ii) It is recognized that not all studies attempted will result in the development of data supportive of the product claims due to invalid tests, failure to obtain cooperators, failure of pest populations to appear in sufficient numbers, climatic considerations, and other factors; limited overages may be incorporated to cover such possibilities.

(iii) Limited experimental programs which may not lead to registration in one or two years are acceptable. However, successive extensions of permits which do not provide appropriate data or do not make adequate progress toward registration may be denied by the Agency.

(iv) As a result of reviews (such as in toxicology, environmental fate, and fish and wildlife), the Agency may find it necessary to reduce quantities below those necessary to develop product performance test results or to deny issuance of a permit, whenever a sufficient potential hazard would be expected to exist or whenever there are insufficient data to determine the possible adverse impact of the pesticide and its use on man or the environment.

(7) Duration. (i) A suitable duration for the permit which is commensurate with the program should be proposed. Permit applications which cover the entire period of proposed experimental work are encouraged rather than applications seeking approval on a year-to-year basis. If the permit period covers more than one season, the applicant should ensure that the proposed testing programs are outlined for each season.

(ii) Proposed programs, when testing is to be conducted over several seasons, need only be outlined in a general manner (approximate studies, acreage, and use rates). Specific details may be supplied

as they become available but must be submitted before the field testing tasks place.

(8) Disposal. (i) A statement describing the method of disposition of any unused pesticide and unused pesticide containers shall be provided. Disposition may include disposal in accordance with 40 CFR Parts 165 and 257, or return of the product to the permittee. The permittee may dispose of or store the unused pesticide and containers in accordance with 40 CFR Parts 165 and 257 or, if the product is currently registered, he may relabel it and use it in accordance with the registered label.

(ii) It is the responsibility of the permittee to ensure that pesticide containers are returned to the permittee for disposal or that instructions are given to the participant and/or cooperator for proper disposal. In the case of the latter, such instructions shall also be stated in the program and shall be consistent with criteria and standards issued pursuant to the Resource Conservation and Recovery Act (P.L. 94-580) in 40 CFR Parts 165 and 257.

(b) Agency and institutional programs. Research agencies and educational institutions may request an "experimental program" under an experimental use permit to cover the testing of those pesticides and use patterns which comprise the research program of the agency or institution. Such a program should list the pesticide(s) to be tested, the use pattern(s), and acreage or sites to be employed for each use pattern.

(c) Inadequate programs. Programs submitted for Agency review and found inadequate (e.g., lack of personnel to carry out the program, or lack of detailed program) will be deemed unacceptable and an experimental permit will not be granted.

§ 111-4 Permit.

(a) Issuance. A permit will be issued only after a review of the data submitted or referenced in support of it has been completed by the Agency and a determination has been made that conditions set forth in all sections of this Subdivision have been met.

(1) A permit will be issued subject to such instructions as necessary to ensure that:

(i) There is adequate control over the use of the experimental compound;

(ii) The use will not result in an unreasonable adverse effect on man or the environment; and

(iii) Data necessary to register a compound or ensure that labeling is in compliance with FIFRA sec. 2(q) will be gathered;

(2) Permits will be issued subject to: a specified time period; a specified quantity of product; use in specified states; use in accordance with acceptable labeling and experimental program; and the condition that the specified studies requested are conducted during the experimental program.

(3) Prior to shipment to or use in a state, a permittee must consult with the pesticide regulatory officials of the state and obtain a state permit or license if such is required.

(b) Amendments, extensions, and renewals. (1) Amendments. Prior to shipment to unauthorized states, shipment of unauthorized quantities of product, or use of a product contrary to accepted labeling and/or program, an applicant must request in writing and receive written permission to amend the permit.

(2) Extensions. Extensions of time for an experimental use permit may be requested.

(i) A request to extend a permit shall be accompanied by the proper application form and supporting data as outlined in § 111-1(a). Information previously submitted for sections A, C, D, E, and F on the application form may be referenced to the original permit if appropriate. Sections B and G may not be referenced.

(ii) All data pertaining to registration requirements which have been collected to date under the original permit must be submitted. The request should be accompanied by an up-to-date report detailing shipping and testing under the original permit.

(3) Renewals. A request for renewal of a permit will be considered in the same manner as a request for extension.

(4) Unconducted programs. If an experimental program is not conducted for any reason, approval of that same program for the following year will be done on a pro forma basis without additional review.

(5) Tolerance extension/renewal. A permit established in connection with a temporary tolerance or temporary exemption from a tolerance and/or food or feed additive tolerance may be extended or renewed only upon extension or renewal of the temporary tolerance or temporary exemption from a tolerance and/or food or feed additive tolerance (unless full tolerances or exemptions from a tolerance have been established in the interim). Refer to 40 CFR 180.33(b) for the fees involved. Note: if the extension/ renewal does not involve any additional quantity of pesticide (i.e., a time extension to utilize material unused from the original permit), a fee is not required.

(c) Maintenance of records. All producers of pesticides produced pursuant to an experimental use permit shall maintain records in accordance with 40 CFR Part 169.

§ 111-5 Importation of pesticides for experimental use.

(a) Technical materials may be imported without registration in sufficient quantities to formulate a pesticide for which an experimental use permit has been requested if the applicant for such permit states that such importation will occur. The labeling of the technical material must comply with FIFRA sec. 2(q), and the material must be imported in accordance with the regulations for importing pesticides and devices, as delineated in 19 CFR 12.110.

(b) Formulated products imported without registration may not be moved within the United States prior to being labeled with an approved label from the Agency (refer to § 111-2 of this subdivision).

§ 111-6 Program surveillance and reporting of data.

(a) Program surveillance and reporting of adverse effects. The permittee shall supervise the test program and evaluate the results of testing at each site of application. The permittee shall also report immediately to the Agency any adverse effects resulting from use of, or exposure to, the pesticide.

(b) Reports to EPA. Reports submitted to the Agency shall include the following:

(1) Name and street address of the shipper of any pesticide covered by the permit, and place or places from which shipped;

(2) The names, addresses, and phone numbers of all consignees and cooperators;

(3) Amount of each shipment;

(4) Total quantities of technical material imported, if any, to formulate pesticides covered by the permit;

(5) List of states into which shipments were made;

(6) A description of the disposal action for all used pesticide containers and any unused pesticides, including amount disposed of

and the method and site of disposition (the disposal of pesticides and their containers that are identified as hazardous waste pursuant to 40 CFR Part 250 shall be reported to the Agency's Regional Administrator in accordance with 40 CFR secs. 250.23 and 250.43-5.);

(7) The method of disposition of affected food and/or feed; and

(8) A full accounting of all material allocated under the permit, e.g., shipped, used, returned, or destroyed.

(c) Reports to USDA. In the case of any meat-producing animals or birds that receive a direct application of any experimental use pesticide and will not be destroyed, the name and location of the packing plant where the animals will be processed shall be sent to the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Washington, D.C. 20250, at least 10 days before the animals are to be shipped for slaughter. This requirement may be waived, on request, by the U.S. Department of Agriculture. These provisions do not exempt treated food-producing animals and their products from compliance with other applicable inspection requirements.

(d) Failure to submit reports. Failure to submit required reports constitutes grounds for revocation of the permit, and may constitute a violation of sec. 12(a)(2)(N) of FIFRA.

(e) Advance notification. For the purpose of supervising the use of experimental use pesticides, the Agency may require the permittee or any participant to give reasonable advance notification to EPA or the state of the intended dates, times, and sites on which such experimental use pesticide will be applied.

(f) Entry and inspection. The permittee, participants, and cooperators in the experimental use program shall permit any authorized representative of the EPA or state enforcement personnel, upon presentation of official identification, entry, at any reasonable time, to any premises involved in the testing program, to inspect and to determine whether there has been compliance with the terms and conditions of the permit.

§ 111-7 Refusal to issue and revocation.

(a) Refusal to issue. Whenever it is determined that issuance of an experimental use permit is not justified, or that the issuance of such a permit would cause unreasonable adverse effects on humans or the environment, or that for any other reason provided under the law a permit shall not be issued, the applicant shall be notified

in writing. The applicant may then request a waiver of such conditions within 30 days after receipt of a letter outlining the reasons for refusal, or he may request that the permit application be placed in abeyance while information necessary to correct the original application and bring it into compliance with these regulations is being obtained. [Refer to § 111-1(b)(2) of this subdivision.]

(b) Revocation. (1) The Administrator may revoke an experimental use permit if:

(i) The terms or conditions of the permit are being violated;

(ii) The terms or conditions of the permit are inadequate to avoid unreasonable adverse effects on man and the environment;

(iii) The tolerance or the exemption from the requirement for a tolerance will be inadequate to protect the public health;

(iv) The labeling is not adequate to protect applicators, users, or workers exposed to a pesticide; or

(v) The applicant has failed to meet any provision of §§ 110-1 through 113-1 of this subdivision.

(2) The Administrator will notify the permittee in writing of such revocation.

(3) The permittee shall notify all participants of such revocation as soon as possible after he receives notice of revocation.

(4) The revocation of a permit shall not preclude the Administrator from initiating civil or criminal sanctions for violations of the permit conditions or as otherwise authorized by law.

(c) Conference. In the event that an applicant for an experimental use permit wishes to contest the refusal to issue an experimental use permit, or a permittee wishes to contest the revocation of a permit, he must, within twenty days after receipt of notice of such refusal or revocation, file with the Administrator a written request for an opportunity to confer with the Administrator or his designee. Within twenty days after such conference, the applicant or permittee will be notified of the Administrator's final decision.

§ 111-8 Publication.

(a) Notice of receipt of application. The Administrator shall publish a notice in the Federal Register of receipt of an

application for an experimental use permit upon finding that issuance of the experimental use permit may be of regional or national significance. This notice shall include:

(1) The name and address of the applicant;

(2) The active ingredient(s);

(3) The use pattern(s);

(4) The quantity of pesticide requested;

(5) The total acreage (sites) to be treated;

(6) The location of area(s) of application(s);

(7) The proposed duration of the permit;

(8) A statement soliciting comments from any interested persons regarding the application; and

(9) Any other information pertinent to the regional or national significance of the permit.

(b) Public hearing. The Administrator may hold a public hearing in accordance with sec. 21(b) of FIFRA, and publish notice in the Federal Register of the date and location of the hearing, when he determines that there is sufficient interest in the application to warrant a hearing based upon the comments received in response to the Notice of Receipt of an Application, or that a hearing would otherwise be in the public interest.

(c) Issuance of experimental use permit. The Administrator shall give prompt notice in the Federal Register of the issuance of an experimental use permit. The notice shall include:

(1) The name and address of the permittee;

(2) The active ingredient(s);

(3) The use pattern(s);

(4) The quantity of pesticide authorized;

(5) The total acreage (or sites) to be treated;

(6) The states where application will take place;

(7) Effective dates of the permit; and

(8) A statement indicating where the experimental use permit is available for public inspection.

(d) Availability of permit information. In accordance with sec. 10 of FIFRA, the only information which will be made available to the public will be labeling for the product and that part of the letter of issuance for the experimental use permit dealing with the items listed in (1) through (5) below. (All other information must be obtained through procedures set forth in the Freedom of Information Act; see 40 CFR Part 2.)

(1) Effective dates;

(2) Quantity of product granted;

(3) Tolerances established (if any);

(4) States to which the product may be sent; and

(5) Statements concerning the accepted labeling.

## Series 112: DATA IN SUPPORT OF AN EXPERIMENTAL USE PERMIT

### § 112-1 General requirements.

(a) Data requirements. (1) The following types of data are required in the support of an application for an experimental use permit:

(i) General chemistry information on the product; refer to § 112-2;

(ii) Environmental fate data; refer to § 112-3;

(iii) Toxicology data; refer to § 112-4;

(iv) Nontarget organisms data; refer to § 112-5; and

(v) Pesticide product performance data; refer to § 112-6.

(2) Data submitted in connection with an application for an experimental use permit often point out possible problems with the pesticide's use or disposal, and may therefore cause the Agency to request additional data that are not routinely required. The Agency intends to require data beyond those set forth in these guidelines if such data are necessary for the Agency to determine whether the proposed use(s) will result in any unreasonable hazards to man or the environment.

(3) Data need not be submitted or referenced when testing an EPA-registered product unless the testing involves:

(i) A new food use; or

(ii) A proposed use which might result in residues of the active ingredient being present in food or feed at a level higher than that of an established tolerance.

(4) Due to the limited time for reviewing permits mandated by the Act and the limited exposure and controlled use conditions that must exist during the permit period:

(i) Acceptance of data submitted in support of an experimental use permit does not necessarily mean that these same data will be acceptable in support of registration. The Agency will try, however, to notify applicants if data are acceptable in support of an experimental use permit but not for registration.

(ii) Data submitted in connection with an experimental use

permit but which are not necessary to support the permit may not have been reviewed. Applicants should not assume that all such submitted data have been reviewed and found acceptable.

(5) If data required by this subdivision to obtain an experimental use permit would not be required in order to obtain a conditional registration under FIFRA sec. 3(c)(7) and 40 CFR 162.18-2, these data need not be submitted to support the application for a permit.

(b) Waivers and deviations. (1) Waivers. Some studies required in §§ 112-2 through -6 may not be necessary, depending on the pesticide being tested, its proposed use, and the quantity of pesticide to be tested. Section 5(a) of FIFRA allows an applicant to request a waiver of the requirement to submit data if he feels that such data are not pertinent to his particular product. It is the responsibility of the applicant to decide which studies may not be necessary and to submit an appropriate rationale to support his decision. Such requests will be reviewed by the Agency on a case-by-case basis.

(2) Deviations. The Agency fully realizes that the standards for acceptable testing specified in these guidelines are not always appropriate for every product. For certain products, some test standards may be wholly inapplicable. At times, the standards for conducting a test may have to be modified to accommodate unusual products. In these cases, the Agency will review deviations from test standards.

(c) Endangered/threatened species. The potential hazards, due to proposed pesticide use(s) or disposal during an experimental use permit, to endangered or threatened plants and animals, or their critical habitats, will be considered by the Agency. In coordination with the U.S. Department of Interior, the Agency will evaluate all available information to determine if the permit program should be approved, modified, or denied. The applicant should carefully determine whether geographical areas selected for the permit activities contain, or are suspected to contain, threatened or endangered plants or animals or their critical habitats. It is suggested that the applicant check with applicable State/Federal agencies prior to filing application for an experimental use permit to ensure that action under the permit will not result in adverse effects on endangered or threatened species.

(d) New uses for registered pesticides. Agency policy intends that, in no instance, will the data requirements to support an application for a permit covering a new use of an already-registered pesticide be more stringent than the data requirements to support the conditional registration of that new use.

§ 112-2 Product chemistry.

(a) General. All product chemistry studies required by this section should be carried out as specified in Subdivision D of these guidelines or by comparable protocols.

(b) Data requirements. Product chemistry requirements for support of an experimental use permit shall include the following:

(1) For all uses:

(i) Product identity; refer to § 61-1(a) for required information.

(ii) Disclosure of ingredients; refer to § 61-1(b) for required information.

(iii) A description of the manufacturing process; refer to § 61-2 for required information. For a pesticide chemical which is in the development stage (not in full scale production), a schematic diagram and/or brief description of the manufacturing process will suffice.

(iv) Product analytical methods and data; refer to § 62-1 for required information. For a pesticide chemical which is in the developmental stage, a rudimentary product analytical method and data are required.

(v) Physical and chemical properties; refer to §§ 64-1 through 21 for required information.

(vi) Submittal of samples; refer to § 65-1 for required information.

(vii) A discussion of unintentional ingredients (refer to § 61-3) shall be submitted to the extent that this information is available.

(2) In addition to those studies required in paragraph (b)(1) of this section, a declaration and certification of ingredient limits in accordance with § 62-2 will be required for products with food uses, to the extent that this information is available.

§ 112-3 Environmental fate.

(a) General. All environmental fate studies required by this section should be carried out as specified by Subdivision N of these guidelines or comparable protocols.

(b) Data requirements. Environmental fate data requirements for support of an experimental use permit shall include the following studies:

(1) Terrestrial (noncrop, orchard, field and vegetable crop) uses. The following data are required for pesticides to be used on orchard, field, and vegetable crops and in noncrop areas:

(i) A hydrolysis study; refer to § 161-1 for required information.

(ii) An aerobic soil metabolism study; refer to § 162-2 for required information.

(iii) A confined accumulation study on rotational crops, for uses involving crops that are rotated; refer to § 165-1 for required information. In lieu of this study, a crop rotation restriction may be placed on the label.

(iv) On a case-by-case basis, laboratory studies of pesticide accumulation in fish (refer to § 165-4 for required information) only when the criteria specified in paragraph (b)(2) of that section are met or exceeded.

(2) Forestry uses. The following data are required for pesti cides to be used in forests, forest tree nurseries, or in reforestation sites:

(i) A hydrolysis study; refer to § 161-1.

(ii) An aerobic soil metabolism study; refer to § 162-2 for required information.

(iii) On a case-by-case basis, laboratory studies of pesticide accumulation in fish (refer to § 165-4 for required information) only when the criteria specified in paragraph (b)(2) of that section are met or exceeded.

(3) Aquatic uses (food crop). The following data are required for pesticides to be used on aquatic or semiaquatic crops:

(i) A hydrolysis study; refer to § 161-1 for required information;

(ii) An aerobic aquatic metabolism study; refer to § 162-4 for required information; and

(iii) A confined accumulation study on rotational crops, for crops that are rotated; refer to § 165-1 for required information. In lieu of this study, a crop rotation restriction may be placed on the label.

(iv) On a case-by-case basis, laboratory studies of pesticide accumulation in fish (refer to § 165-4 for required information) only when the criteria specified in paragraph (b)(2) of that section are met or exceeded.

(4) Aquatic uses (non-crop). The following data are required for pesticides to be used in or adjacent to any aquatic site other than that used for production of human food or domestic animal feed:

(i) A hydrolysis study; refer to § 161-1 for required information.

(ii) An aerobic aquatic metabolism study; refer to § 162-4 for required information.

(iii) Laboratory studies of pesticide accumulation in fish (refer to § 165-4 for required information) only when the criteria specified in paragraph (b)(2) of that section are met or exceeded.

(5) Aquatic impact uses (direct discharge). The following data are required for pesticides discharged directly into the natural aquatic environment in association with their use or the typical method of disposal of pesticide-treated water:

(i) A hydrolysis study; refer to § 161-1 for required information.

(ii) An aerobic aquatic metabolism study; refer to § 162-4 for required information.

(iii) Laboratory studies of pesticide accumulation in fish (refer to § 165-4 for required information) only when the criteria specified in paragraph (b)(2) of that section are met or exceeded.

(6) Aquatic impact uses (indirect discharge and wastewater treatments). The following data are required for pesticides which would likely be discharged into aquatic environments by indirect means or enter wastewater treatment systems: a hydrolysis study; refer to § 161-1 for required information.

## § 112-4 Toxicity data requirements concerning human and domestic animal hazards.

(a) General. All toxicology studies required by this section concerning human and domestic animal hazards should be carried out as specified in Subdivision F of these guidelines or other comparable protocols. Specifically, comparable studies

conducted in accordance with the toxicology guidelines developed by the Organization for Economic Cooperation and Development (OECD) may also be used to meet the data requirements of this section.

(b) Data requirements. The following toxicity data, with respect to hazards to humans and domestic animals, shall be submitted in an application for an experimental use permit:

(1) All uses. The following are required for all pesticides:

(i) Acute oral LD50 in one species (rat) for the end-use product; refer to § 81-1 for required information;

(ii) Acute dermal LD50 in one species (rabbit) for the end-use product; refer to § 81-2 for required information;

(iii) Primary dermal irritation in one species (rabbit) for the end-use product; refer to § 81-5 for required information;

(iv) Primary eye irritation on one species (rabbit) for the end-use product, if not strongly acidic or strongly alkaline, or if not deemed corrosive or a severe irritant in dermal tests; refer to § 81-4 for required information; and

(v) Other conditional studies as required by paragraph (b)(3) of this section.

(2) Food uses. The following are required where pesticide application will result in the possibility of residues of the pesticide occurring in or on food or feed items.

(i) When all food or feed treated under the permit will be destroyed or used for research purposes, only the toxicity data listed in paragraph (b)(1) of this section will be required.

(ii) When permits are accompanied by a temporary tolerance, food additive tolerance, or exemption from the requirement for a tolerance, the following studies employing the technical grade of each active ingredient in the pesticide product are required:

(A) Two 90-day or longer subchronic oral dosing studies; refer to § 82-1 for required information. A no observed effect level (NOEL) must be demonstrated for one rodent (rat) and one nonrodent species;

(B) A teratology study; refer to § 83-3 for required information;

(C) A battery of three mutagenicity studies to assess gene mutation, chromosome aberrations, and primary DNA damage;

(1) A gene mutation test in bacteria with and without metabolic activation; refer to § 84-2(b) for required information;

(2) An in vivo mammalian cytogenetic test; refer to § 84-3(b) for required information; and

(3) An unscheduled DNA repair synthesis study in mammalian cells with and without metabolic activation, or a sister-chromatid exchange study in mammalian cells with and without metabolic activation; refer to § 84-4(c) or (e), respectively, for required information.

(iii) In cases where the total cumulative theoretical maximal residue contribution ("TMRC" 1/) of all treated crop(s), including contributions from all crops with established and pending tolerances exceeds 50 percent of the maximal permitted intake ("MPI" 2/), the following toxicology studies conducted with the technical material of each active ingredient in the pesticide product shall ordinarily be required.3/ These studies are in addition to those stated in paragraph (b)(2)(ii) of this section:

(A) A one-year (or longer) interim report on a chronic feeding study being performed in accordance with § 83-1. However, it is not required that animals in this study be sacrificed for the sole purpose of satisfying this requirement. Data reporting and evaluation of the information in this report should be in the format specified in § 83-1. This interim report should include the following:

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1/ "TMRC" is the amount of a chemical residue which is calculated to remain in an "average" adult human diet. The "average" diet weighs 1.5 kg and is composed of different food items in an amount equal to the calculated average intake for each food item. The TMRC calculation is based on the assumption that each food item contains the maximum level of residue authorized by existing and pending tolerances.

2/ "MPI" is the acceptable allowable daily intake (ADI) times 60 kg (average body weight of humans).

3/ The Agency realizes that the 50 percent limit does not take into account all relevant factors for all proposed experimental uses, particularly those relating to exposure. The Agency, therefore, intends to consider the 50 percent limit as a flexible guidepost subject to reasonable variation on a case-by-case basis.

(1) A complete description of the test substance, the protocol, and the results of all observations and determinations made to date;

(2) All available data on gross observations, body weights, food consumptions, hematology determinations, blood chemistry determinations, and additional tests (if any);

(3) The results of any gross necropsies and available histopathologic data from animals that died or were sacrificed (due to moribundity and/or planned interim sacrifice); and

(B) A first generation (or longer) interim report on a reproduction study being performed in accordance with § 83-4. Data reporting and evaluation of the information in this report should be in the format specified in § 83-4. This interim report should include:

(1) A complete description of the test substance, the protocol, and the results of all observations and determinations made to date;

(2) All available data on gross observations, body weights, maternal data, paternal data, litter data, and additional tests (if any);

(3) All data and reproductive indices up through weaning of all $F_1$ generation animals; and

(4) The results of any gross necropsies and available histopathologic data from animals that died or were sacrificed (due to moribundity and/or planned sacrifice).

(iv) A permit for a new formulation containing an active ingredient which is registered and for which a permanent tolerance, tolerance exemption, or food additive regulation has been established for the proposed use need only be accompanied by the toxicology data required under paragraph (b)(1) of this section. This provision is based, however, on the assumption that the new formulation is to be used in such a manner as to not result in residues in excess of the established levels or not be contrary to the provisions for specific tolerances in 40 CFR Part 180.

(3) Conditional test requirements. The permit application must contain the following toxicity data if those data will be required to support the registration of the pesticide product:

(i) Acute inhalation toxicity study on the end-use product; refer to § 81-3 for required information;

(ii) Acute delayed neurotoxicity study on the technical grade of each active ingredient in the end-use product; refer to § 81-7 for required information; and

(iii) Dermal sensitization study on the end-use product; refer to § 81-6 for required information.

(4) Inert ingredients. If application will result in the possibility of residues occurring in or on food or feed, inert ingredients in the formulated product(s) should be exempted from the requirement of a tolerance (40 CFR 180.1001) unless all food or feed treated under the experimental use permit will be destroyed or used only for experimental research purposes. Inert ingredients which have not been exempted will be handled on a case-by-case basis.

## § 112-5 Data requirements concerning nontarget organism hazards.

(a) General. All toxicity studies required by this section concerning hazards to nontarget organisms should be carried out as specified under Subdivisions E, F, J, and L of these Guidelines or other comparable protocols.

(b) Data requirements. In general, data on hazards to nontarget organisms are not required for indoor uses and those outdoor uses not involving contact with nontarget organisms. Permit application data requirements for pesticides whose outdoor uses involve likely contact with nontarget organisms shall include the following:

(1) Mammal and bird studies. (i) Mammalian LD50 study; this test is generally satisfied by the acute oral toxicity study required by § 112-4(b)(1) of this subdivision, and described in detail in § 81-1 of Subdivision F;

(ii) Avian single dose oral LD50; refer to § 71-1 of Subdivision E for required information;

(iii) Avian dietary LC50 study on two avian species; refer to § 71-2 for required information;

(iv) Fish acute LC50 study on both a cold and warm water species; refer to § 72-1 for required information; and

(v) Acute toxicity to fresh water aquatic invertebrates; refer to § 72-2 for required information.

(2) Nontarget insect studies. (i) Honey bee acute contact LD50 study; refer to § 141-1 of Subdivision L for required information.

(ii) Acute toxicity to aquatic insects study; refer to § 142-1 for required information.

§ 112-6 Product performance.

(a) General. In general, efficacy data will not be required to support the issuance of an experimental use permit.

(b) Exceptions. (1) Initial permits. Efficacy data may be required, on a case-by-case basis, for the following use categories:

(i) Public health uses dealing with microscopic organisms; and

(ii) Use of cancelled or suspended pesticides.

(2) Extensions, renewals, and amendments. Summaries of product performance data collected under an experimental use permit may be requested on a case-by-case basis by the Agency for purposes of making:

(i) Determinations as to the need for additional quantities of product requested by the applicant;

(ii) Evaluations of requests for permit extensions; and

(iii) Assessments of requests for permit renewals.